Personalized Tourniquet Systems

EMT EMERGENCY and MILITARY TOURNIQUET

IMPORTANT! **READ THIS INFORMATION BEFORE USING TOURNIQUET AND SAVE FOR FUTURE REFERENCE**

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PRODUCT DESCRIPTION

The Delfi EMT Emergency and Military Tourniquet (EMT) consists of a heat sealed black nylon inflatable bladder, a clamp assembly permanently attached to one end of the bladder, and a hand bulb inflator permanently attached to the bladder via a flexible hose. A twist-type air release valve is included between the hand bulb inflator and the bladder to allow deflation of the bladder. The clamp secures a portion of the bladder around the limb and seals the bladder across its width, such that the portion of the bladder surrounding the limb inflates and the remaining portion of the bladder does not inflate. The EMT is available in one size able to encircle a 3 to 34 inch circumference.

The EMT is used in military combat care, emergency medicine, and accident situations where electrical power is not available, on persons whose limb circumference (including any clothing under the tourniquet) is within the range of the tourniquet. The tourniquet may be applied by an assisting person or self-applied by the injured person. This tourniquet is intended for emergency use only in situations where the injured person is at risk of death due to exsanguination and where conventional emergency medicine techniques (e.g. pressure bandages) are impossible to apply or are ineffective at controlling blood loss, and the person applying the tourniquet has been trained in its use.

INDICATIONS AND USAGE

The purpose of an emergency tourniquet is to exert enough pressure on a limb to stop the arterial blood flow in the limb in order to control blood loss from a wound positioned distal to the tourniquet. Emergency tourniquets should be used only when other methods of controlling blood loss (such as pressure bandages) are ineffective or cannot be used, or as indicated by the policies of the user's practice setting. The minimum pressure required to stop arterial blood flow should be used and the tourniquet should be used for the minimum amount of time possible.

WARNING! Pressure may fall or rise at any time while the tourniquet is inflated depending on the conditions of each individual case. See WARNINGS section below for more information.

CONTRAINDICATIONS

The EMT is contraindicated if death by exsanguination can be prevented by other conventional emergency medicine techniques (e.g. pressure bandages). This decision rests solely with the user and should be made in accordance with the policies of the user's practice setting.

WARNINGS

- **The EMT requires manual regulation of the tourniquet pressure. The EMT is not a surgical tourniquet. Unlike most surgical tourniquet systems, the EMT does not indicate tourniquet pressure and time, and does not automatically increase or decrease pressure in response to changing conditions unique to each case (such as limb movement, shifting of the tourniquet on the limb, changes in the limb properties, and temperature changes). The user must be fully aware of the following:**

  - Use the EMT in emergency conditions only when conventional emergency medicine techniques (e.g. pressure bandages) of preventing death due to exsanguination cannot be used or are not effective, and when electrical power is not available.
  - Transfer the injured person to a tourniquet system with pressure and time indicators and warnings as soon as possible, and if available transfer to a self-regulating surgical tourniquet system.
  - Pressure may fall or rise at any time while the tourniquet is inflated depending on the conditions of each individual case.
  - Inflate the tourniquet to the minimum pressure required to stop arterial bleeding distal to the tourniquet and a distal pulse can no longer be felt. Required pressure is unique to every case and depends on tourniquet location, snugness of tourniquet application, limb size and properties, patient physiology, and other factors.
  - Monitor the injured person continuously for signs of arterial or venous bleeding, or venous engorgement of the limb distal to the tourniquet.
  - If bleeding resumes, increase tourniquet pressure the minimum amount required to stop bleeding and a distal pulse from being felt.
  - If you suspect that tourniquet pressure is higher than necessary, slowly decrease pressure using the twist-type air release valve only until signs of bleeding or a distal pulse resume, then immediately increase pressure until bleeding or a distal pulse stops.
  - To minimize the chance of further injury to the limb, minimize the time that the tourniquet is continuously inflated on the limb. Deflate and remove the tourniquet as soon as bleeding can be controlled by alternate means.
  - If permitted by the policies of the user's practice setting, reperfusion of the limb may be performed by deflating and re-inflating the tourniquet.

- **This product is subject to wear and deteriorates with use. It is essential to inspect this device after each use before repacking for reuse (see UTILIZATION for instructions on inspection). If the tourniquet fails to pass inspection, it is no longer usable and must be discarded. Use of a damaged tourniquet could result in one or more of the following events: loss of tourniquet pressure; release of the tourniquet from around the patient's limb; movement of the tourniquet on the patient's limb; or excessive leakage of tourniquet pressure. Some of these failures could cause catastrophic injury, including death, to the patient by releasing blood.**
- **The tourniquet must be applied at the proper location on the limb, for an appropriate period of time, and within the appropriate pressure range, all determined solely by the user (See UTILIZATION). Application of the tourniquet over the area of the peroneal nerve (the knee or ankle), or over the area of the ulnar nerve (the elbow) may produce nerve/bone impingement resulting in nerve damage or paralysis.**
- **Do not readjust an already positioned tourniquet by rotation. Rotation produces shearing forces which may damage the underlying tissues.**
- **Never puncture the tourniquet. Therefore, sharp objects used near the tourniquet must be handled with care.**
- **Ensure that the twist-type air release valve is closed prior to inflating the tourniquet and when the tourniquet is re-packed for future use.**
- **When closing the twist-type air release valve do not over-tighten the valve cap. Using excess force to turn the valve cap more than 1/8 turn past the point where resistance is first felt may damage the valve.**
- **When opening the twist-type air release valve do not turn the valve cap past the point where resistance is felt, to do so may result in the valve cap separating from the valve body.**
- **Ensure that debris does not enter and obstruct the hand bulb inflator intake (hole in the end of the bulb opposite the twist-type air release valve).**

PRECAUTIONS

The following precautions should be observed when the EMT tourniquet is used:

When using a tourniquet on patients with sickle cell disease or trait, severe post-tourniquet pain may result in the affected limb which may be caused by sickling of cells.

Do not allow fluids to flow and collect under the tourniquet where they may cause chemical burns.

If recommended by the policies of the user's practice setting, the limb may be exsanguinated prior to tourniquet inflation.

Inflation must be done as rapidly as possible to occlude arteries and veins simultaneously.

Heat generated by outside sources is not dissipated in limbs under tourniquet control and tissue may be subject to drying or trauma. Frequent irrigation, and special draping are recommended to reduce the risk of thermal damage.

Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves.

Tourniquet paralysis with possible irreversible functional loss may result from either excessive or insufficient pressure. Prolonged tourniquet time can also produce changes in the coagulability of the blood with an increase in clotting time. In severe cases, pooling of blood in the edemic limb may cause cardiac arrest and death.

Observe the tourniquet during inflation and check periodically while inflated to ensure the tourniquet does not move on the patient's limb to a position that may lead to nerve/bone impingement (for example at the ankle, knee, or elbow), or a position causing bleeding to resume. If the tourniquet does move on the limb to an unsafe position, apply a pressure dressing to the wound, then deflate and reapply the tourniquet in the proper position.

Whenever the tourniquet pressure is released, the wound must be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level and the circulation should be checked.

Completely remove the deflated tourniquet and any underlying padding immediately following tourniquet deflation. Even the slightest impedance of venous return may lead to congestion and pooling of blood at the wound site.

ADVERSE EFFECTS

A dull, aching pain (tourniquet pain) may develop throughout the limb following tourniquet use. Stiffness, weakness, reactive hyperemia, and skin discoloration may also occur to some degree in all patients after tourniquet use.

Pathophysioiogical changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissue occur and become significant after about 1 1 /2 hours of tourniquet use. Symptoms of tourniquet paralysis are: motor paralysis and loss of the sense of touch, pressure, and proprioceptive responses.

Continued blood loss after tourniquet application may be caused by:

1. Inadequate tourniquet pressure allowing arterial flow to enter the limb. (See UTILIZATION and WARNINGS)

2. Blood entering through the nutrient vessels of the long bones (such as the humerus).

UTILIZATION

NOTE: Utilization of this tourniquet should be governed by the policies of the user's practice setting.

Limb Size:

The EMT can accommodate limbs from 3" to 34" in circumference (including any clothing that cannot be removed from limb in the area under the applied tourniquet). On larger limbs, the stiffer pull-tab area at the end of the bladder will not pass completely through the clamp and extend beyond the edge of the clamp assembly and the tourniquet cannot be used.

Tourniquet Application:

The EMT must be applied proximal to the wound and, if possible, should be applied at the largest circumference part of the limb to allow as much tissue as possible to lie between the tourniquet and any nerves or vascular structures susceptible to damage. The optimum positions as reported in the medical literature are the upper arm, the proximal portion of the thigh and the mid-calf region.

1. Remove clothing from the limb if possible. A tourniquet that is applied over thick material or clothing will require more pressure to stop blood flow.
2. Unpack and unroll the EMT.
3. Position the tourniquet proximal to the wound by passing the looped tourniquet over the distal end of the injured limb (see Fig. 1). **If access over the limb is impossible**, unthread the tourniquet bladder from the clamp (Fig. 1a), wrap the bladder around the limb, and rethread the bladder through the clamp (Fig. 1b).
4. Ensure that the tourniquet is not twisted. Pull the loose end of the tourniquet away from the limb until it is snug (Fig. 2), then pull at an angle towards the D-shaped portion of the clamp to increase snugness (see Fig 3). Apply the tourniquet snugly. A tourniquet that is applied too loosely will require more pressure to stop blood flow.
5. Close the clamp by squeezing (see Fig 4).
6. Inflate the tourniquet as described in the following section.
7. If possible, roll and stow the portion of the bladder that does not encircle the limb.

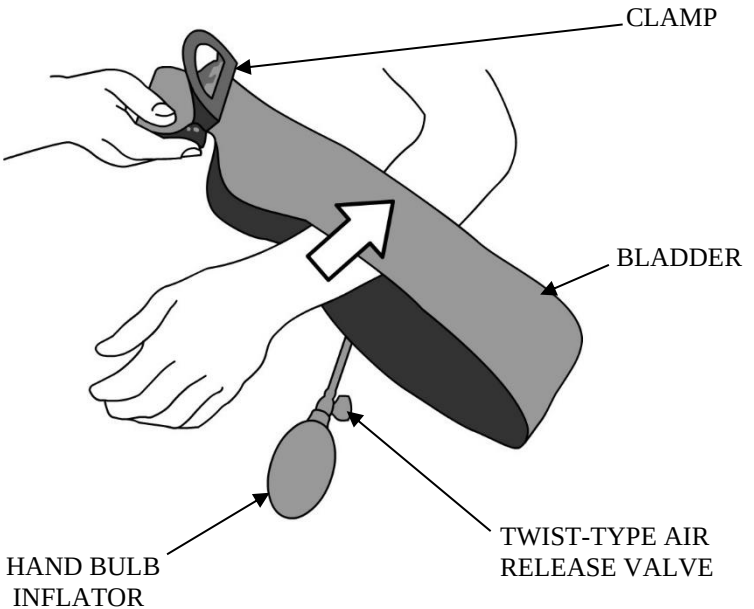
CLAMP
BLADDER
HAND BULB
INFLATOR
TWIST-TYPE AIR
RELEASE VALVE

FIGURE 1

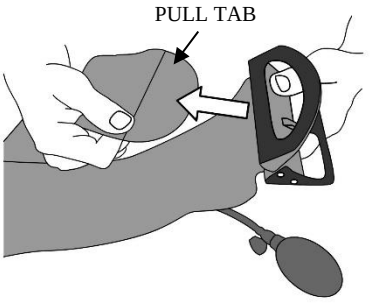

FIGURE 1a

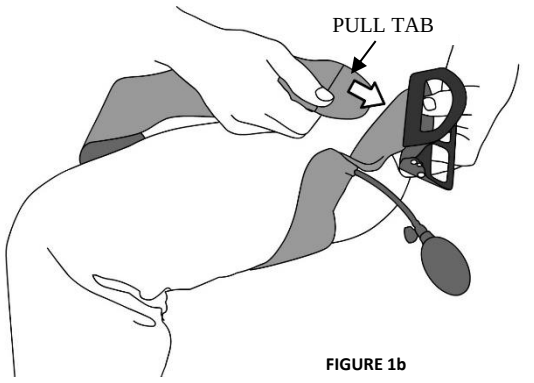

FIGURE 1b

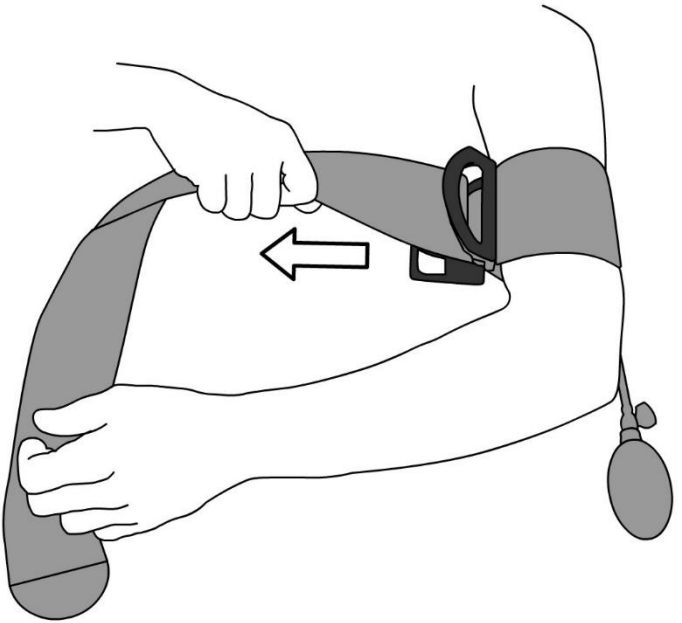

FIGURE 2

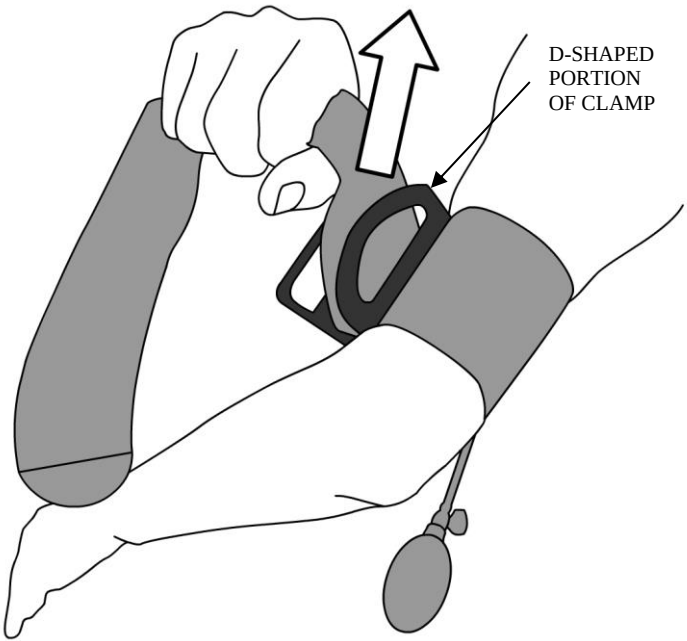

FIGURE 3

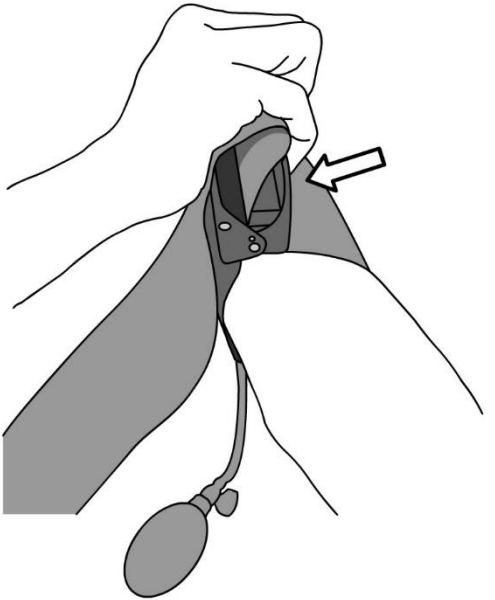

FIGURE 4

Inflation and Pressure Setting:

Ensure that the twist-type air release valve is closed and inflate the tourniquet by squeezing the hand bulb inflator repeatedly until bleeding stops. Note the time at which tourniquet inflation stops bleeding. Monitor the wound frequently and increase pressure if bleeding begins again.

- Pressure may fall or rise at any time while the tourniquet is inflated depending on the conditions of each individual case.
- Inflate the tourniquet to the minimum pressure required to stop arterial bleeding distal to the tourniquet and a distal pulse can no longer be felt. Required pressure is unique to every case and depends on tourniquet location, snugness of tourniquet application, limb size and properties, patient physiology, and other factors.
- Monitor the injured person continuously for signs of arterial or venous bleeding, or venous engorgement of the limb distal to the tourniquet.
- If bleeding resumes, increase tourniquet pressure the minimum amount required to stop bleeding and a distal pulse from being felt.
- If it is suspected that tourniquet pressure is higher than necessary, slowly decrease pressure using the twist-type air release valve only until signs of bleeding resume, then immediately increase pressure until bleeding stops.

Tourniquet Time:

To minimize the chance of further injury to the limb, minimize the time that the tourniquet is continuously inflated on the limb. If permitted by the policies of the user's practice setting, reperfusion of the limb may be performed by deflating and re-inflating the tourniquet.

Tourniquet Removal:

Deflate the tourniquet by opening the twist-type air release valve. When the tourniquet has completely deflated open the clamp and remove the tourniquet from the limb.

Whenever the tourniquet pressure is released, the wound must be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. Transient pain upon tourniquet release can be lessened by elevation of the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level and the circulation checked. It is important that the tourniquet and any underlying padding be removed immediately following deflation to prevent any residual impairment of blood flow in the limb after tourniquet deflation. The time of tourniquet

removal should be noted, and the circulation of the limb should be carefully checked to assure that circulation has been fully restored.

Cleaning and Disinfecting:

The tourniquet may be cleaned in lukewarm water and an alkaline detergent (formulated to possess good blood dissolving characteristics) and rinsed thoroughly. A soft hand brush may be used to remove encrusted material. Do not immerse the tourniquet and do not allow fluid to enter the hand bulb inflator. The cleaned tourniquet should be allowed to drip dry at room temperature. The tourniquet must not be sterilized by gas or steam methods. The tourniquet must be disinfected according to the institution's disinfecting procedures to preserve the clean and disinfected state of the tourniquet.

Inspection after use:

This product is subject to wear and deteriorates with use. After each use, it is essential to inspect the tourniquet before the next use. The following is a list of items to check.

1. Has the tourniquet been cleaned thoroughly after the previous use?
2. After cleaning, is there any obvious discoloration remaining due to blood or residue remaining from previous use that could be a potential source of contamination?
3. Is there any physical damage to the tourniquet (for example, rips, tears, or holes)?
4. Is the hose, twist-type air release valve assembly, or hand bulb inflator cracked or worn?
5. Inflate the tourniquet. Are there any leaks in the tourniquet or air release valve assembly?
6. Is there any other physical change or damage to the tourniquet that would compromise the tourniquet's ability to maintain pressure and stop blood flow?

<u>If any of the above conditions are present the tourniquet is no longer usable and must be discarded.</u>
See WARNINGS for a description of the possible consequences of using a damaged tourniquet. These consequences include the possibility of catastrophic injury, including death, to the patient due to the release of blood.

Storage:

Store the tourniquet in a clean, dry area. Do not store the tourniquet with the clamp closed or with the tourniquet wet. The clean and disinfected tourniquet must be stored according to the institution's storage procedures.
If required, rethread the loose end of the EMT bladder through the clamp (as shown in Fig. 1b). Ensure that the twist-type air release valve is closed. With the clamp in the open position, stow the inflation bulb in the space between the two clamp halves and roll the bladder loosely around the clamp. The tourniquet can also be stored laying flat with the clamp in the open position.

SYMBOLOGY

IFUs and Symbol Glossary
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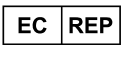

PRODUCT REPORTING

Notify Customer Service Department, Delfi Medical Innovations, at 1-800-933-3022 or via www.delfimedical.com. Please provide details about the nature of the problem and include the product serial number or lot number. Upon receipt of this information, Delfi will provide assistance for resolution or a return shipping authorization.

European Union customers: Any serious incident that has occurred in relation to the device should be reported to Delfi and the competent authority of the Member State in which the user and/or patient is established.

WARRANTY INFORMATION: Please contact Delfi for warranty information.

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